DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

#42

JUL 24 1998

Re: AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION
Docket No.: 97E-0290

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U.S. PATENT AND TRADEMARK OFFICE
ASSISTANT SECRETARY AND COMMISSIONER

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,912,155, filed by Albemarle Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION, the food additive claimed by the patent.

The total length of the regulatory review period for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION is 2,930 days. Of this time, 935 days occurred during the testing phase and 1,995 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a major health or environmental effects test ("test") involving this food additive product was begun: January 9, 1989.

   The applicant claims July 21, 1986, as the date the test was begun. However, FDA records indicate that the test was begun on January 9, 1989.

2. The date the petition requesting the issuance of a regulation for use of the additive ("petition") was initially submitted with respect to the food additive product under section 409 of the Federal Food, Drug and Cosmetic Act: August 1, 1991.

   FDA has verified the applicant's claim that the petition was initially submitted on August 1, 1991.

3. The date the petition became effective: January 15, 1997.

   FDA has verified the applicant's claim that the regulation for the additive became effective/commercial marketing was permitted on January 15, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Teresa Stanek Rea
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